

**REMARKS**

**I. INTRODUCTION**

Fig. 2 has been amended as provided herewith on a separate "Replacement Sheet." Claim 41 has been amended above but not for any reason relating to patentability thereof. Claims 1-7, 9, 11-31, 33-36 and 40-43 are under consideration in the above-referenced application. Provided above, please find a claim listing indicating the amendment to claim 41 on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

**II. OBJECTION TO DRAWINGS SHOULD BE WITHDRAWN**

The drawings have been objected to by the Examiner as excluding a reference to the interferometer 14 indicated in the specification of the present application in paragraph [0036]. As the Examiner shall ascertain, Fig. 2 has been amended as provided herewith on a separate "Replacement Sheet" to show reference 14 for the interferometer therein. Accordingly, the objection to the drawings is now moot, and should therefore be withdrawn.

**III. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 103(a) SHOULD BE WITHDRAWN**

Claims 1, 2, 4, 8, 36 and 43 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Johannes F. de Boer et al., "Imaging thermally damaged tissue by polarization sensitive optical coherence tomography", Optics Express 212, Vol. 3, No. 6., September 1998 (the "de Boer Publication"). Claims 1-7, 9-11, 16-18, 21, 23, 27, 29, 30,

31, 35, 36, 40, 41 stand rejected under 35 U.S.C. §102(e), as being allegedly anticipated by U.S. Patent No. 6,485,413 issued to Boppart (the “Boppart Patent”). Claims 5 and 26 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the Boppart Patent, in view of U.S. Patent No. 6,111,645 issued to Tearney (the “Tearney Patent”). Claims 22, 24, 28 and 34 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the Boppart Patent. Claim 42 stands rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the Boppart Patent, in view of the Tearney Patent.

**A. Rejections of Claims 5, 22, 24, 26, 28, 34 and 42 in view of Boppart Patent**

With respect to the rejection of claims 5, 22, 24, 26, 28, 34 and 42 under 35 U.S.C. § 103(a) in view of the Boppart Patent, taken alone or in combination with the Tearney Patent, it is respectfully asserted that for at least the reasons set forth herein below, these 35 U.S.C. § 103(a) rejections are improper, and should therefore be withdrawn.

Without addressing whether the Boppart Patent teaches or suggest the subject matter of claims 5, 22, 24, 26, 28, 34 and 42 as asserted by the Examiner, Applicants respectfully assert that the Boppart Patent, taken alone or in combination with the Tearney Patent, cannot be used to render these claims unpatentable under 35 U.S.C. § 103(a).

In particular, the present application was filed as January 26, 2004, and claims priority from U.S. Application Serial No. 60/442,392 filed January 24, 2003, and the Boppart Patent issued on November 26, 2002. Accordingly, the priority application of the present application was filed less than one (1) year from the issue/publication date of the

Boppart Patent, and thus, the Boppart Patent is being considered by the Examiner as a 35 U.S.C. § 102(e) reference. (See Office Action, p. 3, para. 4).

However, 35 U.S.C. § 103(c) states that:

"Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person."

The present application was assigned by the inventors thereof to The General Hospital Corporation via an assignment which was recorded with the U.S. Patent and Trademark Office (the "Patent Office") at reel/frame 015765/0879 on September 8, 2004. The application which matured into the Boppart Patent was assigned by the inventors thereof to Massachusetts Institute of Technology via an assignment which was recorded with the Patent Office at reel/frame 009174/0876 on May 11, 1998. Thereafter, Massachusetts Institute Of Technology assigned this application which matured into the Boppart Patent to The General Hospital Corporation via an assignment which was recorded with the Patent Office at reel/frame 011801/0817 on May 14, 2001. Thus, both the present application and the Boppart Patent are assigned to The General Hospital Corporation.

Accordingly, because the Boppart Patent is a 35 U.S.C. § 102(e) reference, and since the present application and the Boppart Patent are owned by the same entity (i.e., The General Hospital Corporation), the Boppart Patent cannot be used to reject claims 5, 22, 24, 26, 28, 34 and 42 under 35 U.S.C. § 103(a). Without combining the Boppart Patent with the Tearney Patent, the Tearney Patent fails to teach or suggest the subject matter recited in claims 5, 22, 24, 26, 28, 34 and 42 of the above-referenced application, and the Examiner does not contend that it does.

Therefore, withdrawal of the § 103(a) rejection of claims 5, 22, 24, 26, 28, 34 and 42 is respectfully requested for at least the reasons presented herein above.

**B. Rejection(s) of Claims 1, 18, 24, 30, 41 and 43 and Dependent Claims**

Applicants respectfully assert that the Boppart Patent, taken alone or in combination with the Tearney Patent, fails to teach, suggest or disclose the subject matter recited in independent claims 1, 18, 24, 30, 41 and 43, and the claims which depend from independent claims 1, 18, 24 and 30.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; also see *Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law,

whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the "TSM test"). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, \*21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The de Boer Publication relates a method for imaging thermally damaged tissue by a polarization sensitive optical coherence tomography technique. This was done by imaging a reduction of birefringence in the such tissue. (See de Boer Publication, Abstract).

The Boppart Patent relates to an imaging system for performing forward scanning imaging for application to therapeutic and diagnostic devices used in medical procedures. The imaging system includes forward directed optical coherence tomography (OCT), and non-retroreflected forward scanning OCT. Also interferometric imaging and ranging techniques and fluorescent, Raman, two-photon, and diffuse wave imaging can be used. (See Boppart Patent, Abstract).

As described in the Boppart Patent, light from an optical source 10 is directed to a given position on a specimen to be imaged, ranged, or otherwise measured via a probe module. Interferometric techniques 19 can be used to collect and detect light altered by the internal microstructural features in the specimen in addition to the other techniques mentioned above. The optical beam directed onto the specimen is spatially coherent, having a single-spatial mode, and thus the delivery system can be from a single-mode fiber. The detected light is processed in a receiver processor 38 to extract information on the specimens optical properties as a function of depth or other spatial metrics (e.g., a location of incident beam on the sample). For instance, a reflectivity profile, or plot of the sample reflectivity as a function of depth, can be obtained. (See *id.*, col. 4, Ins. 49-64; and Fig. 1).

In another embodiment described in the Boppart Patent, a frequency tunable optical source is coupled to the interferometer. The receiver processing unit 38 includes photo-detectors which receive signals from the sample and reference reflections and detects any optical interference. The slight time delay between the arrival of these two signals, combined with frequency tuning, results in a beat signal from which the reflectivity or other interferometric profile of the sample's optical properties can be derived using RF spectral analysis techniques. (See *id.*, col. 5, ln. 64 to col. 6, ln. 5). Further, in yet another embodiment of optical spectrum analysis OCT of the Boppart Patent, the source can be a broad bandwidth source coupled to an interferometer. Reflections from the sample/specimen and reference reflection(s) optically interfere at the receiver, which is an optical spectrum analyzer. (See *id.*, col. 6, Ins. 12-16).

i. Independent Claims 1, 18, 24 and 30 and Dependent Claims

Applicants' invention, as recited in independent claim 1, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

an imaging system adapted to receive axial scan radiation based on the axial scan, and to process data relating to the axial scan radiation to identify characteristics of the tissue ...,

**wherein the imaging system identifies characteristics of the tissue by processing the axial scan radiation to provide the characteristics of the tissue, the axial scan radiation including radiation received from the reference arm and radiation received from the sample arm, and comparing the characteristics of the tissue with a database of normalized characteristics of a plurality of tissue types.**

Independent claims 18, 24 and 30 relate to method, storage medium and logic arrangement, respectively, which recite similar subject matter.

Thus, each of independent claims 1, 18, 24 and 30 recites a **comparison of the characteristics of the tissue with a database of normalized characteristics of a plurality of tissue types.**

Turning to the de Boer Publication, this reference makes absolutely no mention, much less teaching, suggestion or disclosure of **the use of any database of normalized characteristics of a plurality of tissue types, or even the comparison of the characteristics of the tissue with such database**, as recited in independent claims 1, 18, 24 and 30. In the Office Action, the Examiner points to Figs. 1 and 4 of the de Boer Publication as allegedly disclosing the receipt of the axially scanned radiation based on the axial scan, and the processing of the data received from the reference and sample arms relating to the axial scan radiation to identify characteristics of the tissue. (See Office Action, p. 3, Ins. 15-18). However, Applicants respectfully assert that the de Boer

Publication does not even make any reference to the use of any database, and moreover the database of normalized characteristics of a plurality of tissue types. Further, it is submitted that the de Boer Publication does not compare the characteristics of the tissue with any such database, and the Examiner does not reference any section of the de Boer Publication to allegedly teach, suggest or disclose such subject matter.

With respect to the Boppart Patent, this reference also has no teaching, suggestion or disclosure of *the use of any database of normalized characteristics of a plurality of tissue types*, or *the comparison of the characteristics of the tissue with such database*, as recited in independent claims 1, 18, 24 and 30 of the above-identified application. In the Office Action, the Examiner points to Figs. 1 and 2, column 1, lines 39-49 and column 5, line 64 to column 6, line 1 to support the contention that the Boppart Patent discloses the receipt of the axially scanned radiation based on the axial scan, and the processing of the data received from the reference and sample arms relating to the axial scan radiation to identify characteristics of the tissue. (See *id.*, p. 4, Ins. 1-3). Then, on page 5 of the Office Action, with respect to the rejection of claims 18 and 30, the Examiner alleges that the Boppart Patent discloses a comparison of "the characteristics of the tissue with an inherent database that contains normalized characteristic of the tissue." (*Id.*, p. 5, Ins. 9-10).

First, each of the independent claims 1, 18, 24 and 30 recites the use of the database of "*normalized characteristics of a plurality of tissue types*", and not of "*the tissue*" as indicated in the Office Action. Second, it is respectfully submitted that the Boppart Patent has absolutely no teaching, suggestion or disclosure of **any database of normalized characteristics** of either the plurality of tissue types (as recited in these

independent claims) or of the tissue (as provided by the Examiner in the Office Action). Third, Applicants respectfully assert that the Boppart Patent does not even reference, much less teach, suggest or disclose the comparison of any characteristics of the tissue with such recited database.

Accordingly, it is respectfully asserted that both the de Boer Publication and the Boppart Patent fail to teach, suggest or disclose the apparatus, method, storage medium and logic arrangement in which **a comparison of the characteristics of the tissue is performed with a database of normalized characteristics of a plurality of tissue types**, as recited in independent claims 1, 18, 24 and 30 of the above-identified application. The Tearney Patent does not cure at least such deficiencies of either the de Boer Publication or the Boppart Patent, and the Examiner does not contend that it does.

Accordingly, Applicants respectfully submit that the de Boer Publication or the Boppart Patent, taken alone or in combination with the Tearney Patent, do not render the subject matter recited in independent claim 1, 18, 24 and 30 anticipated or obvious. The claims which depend from such independent claims are also not taught, suggested or disclosed by the de Boer Publication or the Boppart Patent, taken alone or in combination with the Tearney Patent for at least the same reasons.

ii. Independent Claim 41

Applicants' invention, as recited in independent claim 41, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

... an imaging system adapted to receive axial scan radiation based on the axial scan, receive data relating to the axial scan radiation that is based on at least one of **a spectral domain low-coherence**

**interferometry or an optical frequency domain reflectrometry**, and process the data to automatically identify characteristics of the tissue.

In the Office Action, the Examiner contends that the Boppart Patent discloses "an imaging system adapted to receive axial scan radiation based on the scan, and received data relating to the scan [that] is based on spectral domain." (See Office Action, p. 6, Ins. 2-5). In support of this allegation, the Examiner points to column 6, lines 12-16 of the Boppart Patent, as well as to Figs. 1 and 2, column 1, lines 39-49 and column 5, line 64 to column 6, line 1 thereof.

However, while the Boppart Patent describes the use of optical coherence tomography (OCT) with the systems thereof, this publications provides absolutely no disclosure, much less teaching or suggestion of any imaging system adapted to receive data relating to the axial scan radiation that is based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry, as explicitly recited in independent claim 41. Indeed, Applicants respectfully assert that the Boppart Patent makes absolutely no reference to the spectral domain low-coherence interferometry or an optical frequency domain reflectrometry, much less to any techniques to utilize the same, and the Examiner does not even contend that it does.

Accordingly, it is respectfully asserted that the Boppart Patent fails to disclose the apparatus which comprises an imaging system adapted to receive data relating to the axial scan radiation that is based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry, as explicitly recited in independent claim 41 of the above-identified application.

iii. Independent Claim 43

Applicants' invention, as recited in independent claim 43, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

... **an imaging system adapted to receive the radiation and process unidimensional data relating to the radiation that is based on at least one of a spectral domain low-coherence interferometry or an optical frequency domain reflectrometry to identify characteristics of the tissue.**

In the Office Action, while alleging that the subject matter recited in independent claim 43 is disclosed in the de Boer Publication, the Examiner does not even point to any section of the de Boer Publication to disclose (a) **processing unidimensional data relating to the radiation**, (b) **the radiation being based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry**, and (c) that such **processing is performed to identify characteristics of the tissue**, as explicitly recited in independent claim 43.

First, the de Boer Publication makes absolutely no mention of the receipt of any radiation which is based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry. Indeed, this publication does not reference such modalities. Second, the de Boer Publication does not disclose the processing of unidimensional data which relates to radiation, much less to a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry. It is submitted that the de Boer Publication describes processing multi-dimensional data (e.g., two-dimensional data) and not unidimensional data and especially that such processing is performed to identify the characteristics of the tissue. The de Boer Publication may

perform processing on the multi-dimensional data for image processing, and not for identifying the characteristics of the tissue.

Accordingly, it is respectfully asserted that the de Boer Publication fails to disclose the apparatus which comprises an imaging system adapted to receive the radiation and process unidimensional data relating to the radiation that is based on at least one of a spectral domain low-coherence interferometry or an optical frequency domain reflectrometry to *identify characteristics of the tissue*, as explicitly recited in independent claim 43 of the above-identified application.

iv. Summary

Thus, for at least these reasons, withdrawal of the rejections of independent claims 1, 18, 24, 30, 41 and 43 and the claims which depend therefrom under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested.

IV. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims 1-7, 9, 11-31, 33-36 and 40-43 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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